

## REMARKS

Applicants have amended independent claims 1 and 23 to incorporate the text of claim 13 which was not separately rejected over the art. Accordingly, this amendment to independent claims 1 and 23 would not add new matter. Claims 1 and 23, which have been amended to recite that the *in vitro* assay does not require “a living biological entity,” is supported throughout the specification, including at page 8, lines 1-2 (“Since the present method does not involve any living biological entities. . .”). Claim 3 has been amended to recite dependency from claim 1, and to delete “autograft” so as to further limit claim 1. Claim 4 has been amended to delete the term “about” from the phrase “less than about 3 percent.” Claim 12 has been amended to delete the two occurrences of the phrase “at least one” and to substitute for each the article “a.” Claim 13 has been amended to be limited to a single member (BMP) of its former Markush group that was incorporated into independent claim 1. The BMP of claim 13 is supported by the disclosure in the specification at FIG 1 and the discussion thereof. Claim 14 has been amended to change the plural phrase “combinations thereof” to its singular form “a combination thereof.” Finally, each of claims 12, 13, 14, 19, 20 and 22 have been amended to recite dependency directly from claim 1, rather than indirectly via claim 3. For all these reasons, the amendments to the claims do not add new matter.

### Summary of Bases for Objection/Rejection

Claim 3 is objected to for being in improper dependent form.

Claims 1, 4-22, 31 and 37 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement.

Claims 3-11 are rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite.

Claims 1, 3-6, 19-20, 22-23, 31 and 37 are rejected under 35 U.S.C. §102(b) for allegedly being anticipated by Zhang et al., *A Quantitative Assesment of Osteoinductivity of Human Demineralized Bone Matrix*, Journal of Periodontology, Vol. 68(11), pp. 1076-1084 (Nov. 1997).

The Applicant will address each of the above bases of rejection in sections I - IV, respectively, which follow.

## I. Objection to Claim 3

Claim 3 is objected to for being in improper dependent form. In particular, claim 3 recites dependency from cancelled claim 2. The Patent Office contends that this basis for objection would be rendered moot if claim 3 recited dependency from claim 1. In response, the Applicants have amended claim 3 to recite dependency from claim 1. Accordingly, this basis for objection has been rendered moot.

## II. 35 U.S.C. §112, First Paragraph (Written Description)

Claims 1, 4-22, 31 and 37 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. As its first basis for rejection, the Patent Office contends that there is no support in the originally filed specification for the phrase “does not require [. . .] use of cell-based assays” as recited in claim 1. Claim 23, which recites the phrase “does not require the use of cellular living biological materials,” was not rejected. Accordingly, Applicants have amended claim 1 to delete recitation of “cell-based assays” and to substitute in its place “a living biological entity” as recited in the specification at page 8, lines 1-2 (“Since the present method does not involve any living biological entities. . .”). This phrase parallels the accepted phrase “cellular living biological materials” of claim 23, which has since been amended in conformity with claim 1. For these reasons, this basis for rejection of claim 1 and its dependents has been rendered moot.

Separately, claim 4 is rejected on the basis that “While the specification recites a calcium content less than 3% (page 17, line 22), it fails to recite [a] calcium content less than **about** 3% which differs in scope.” [Official Action at 3; emphasis added in bold.] In response, the Applicants have amended claim 4 to delete recitation of “about.” Accordingly, this basis for rejection has been rendered moot.

Claims 5-22, 31 and 37 stand rejected due to their dependency upon rejected claims 1 or 4. However, as noted above, the stated bases for rejection of claims 1 and 4 for indefiniteness have been rendered moot. Accordingly, the underlying bases for rejection of these dependent claims have also been rendered moot.

### III. 35 U.S.C. §112, Second Paragraph

Claims 1 and 3-11 are rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. In particular, claim 1 is rejected in its recitation of “like implant materials comprising bone.” [Official Action at page 4.] The Patent Office contends that it is “like” implant materials composed of bone. In response, the applicants have amended claim 1 to delete reference to “like” implant materials. Accordingly, this basis for rejection has been rendered moot.

Claim 3 is rejected for reciting in line 1 “said bone implant material.” [Official Action at page 4.] According to the Patent Office, claim 3 depends from cancelled claim 2, but that “the rejection would be nullified if claim 3 was amended to depend from claim 1.” [Official Action at page 4.] Claims 4-11 are rejected based upon their dependency from rejected claim 3. In response, the Applicants have amended claim 3 to recite dependency from claim 1. Accordingly, this basis for rejection of claim 3 and its dependents (claims 4-11) has been rendered moot.

### IV. 35 U.S.C. §102(b) over Zhang

Claims 1, 3-6, 19-20, 22-23, 31 and 37 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Zhang *et al.*, *A Quantitative Assessment of Osteoinductivity of Human Demineralized Bone Matrix*, Journal of Periodontology, Vol. 68(11), pp. 1076-1084 (Nov. 1997). The Examiner alleges that Zhang *et al.* discloses an in vitro method for quantifying the osteoinductive potential of demineralized bone matrix . . . from cadaverous humans before clinical (human) use (allograft) . . . as cited in claims 1 and 23.” [Official Action at page 5, citing to Zhang at the title, abstract, and page 1077, col. 2, second paragraph.] While the in vitro assays of Zhang are in vitro in so far as they are performed in a test tube, they all require living cells. See Zhang at page 1078, col. 1. In contrast, the method of the Applicants invention as recited in independent claims 1 and 23 specifically states that it “does not use a living biological entity.” For this reason alone, claims 1 and 23, and their dependents (claims 3-6, 19-20, 22, 31 and 37), would not be anticipated by Zhang. Because Zhang’s *in vitro* assay requires the use of cells, Applicants’

*in vitro* assay, which does not require the use of cells, would not have been obvious over Zhang at the time that the Applicants' invention was made.

Separately, each of independent claims 1 and 23 recites a Markush group of osteogenic factors which are the analytes of the *in vitro* assay of the claims. None of the analytes is "alkaline phosphatase" (ALP). In contrast, the only "*in vitro*" assay (albeit with cells) disclosed in Zhang is for alkaline phosphatase. See Zhang at page 1078, cols. 1-2. For this reason also, claims 1 and 23, and their dependents (claims 3-6, 19-20, 22, 31 and 37), would not be anticipated by Zhang.

Moreover, there is no evidence that alkaline phosphatase is an art recognized equivalent of any of the growth factors of the Applicants' Markush group. For this reason, claims 1 and 23 and their dependents (claims 3-6, 19-20, 22, 31 and 37) would not have been obvious over Zhang.

## SUMMARY

Claims 1, 3-23, 31 and 37 stand rejected. In view of the amendments and arguments provided herein, the objection to claim 3 has been rendered moot. In view of the amendments and arguments provided herein, the rejection of claims 1, 4-22, 31 and 37 under 35 U.S.C. §112, first paragraph, for failure to satisfy the written description requirement have been rendered moot. In view of the amendments and arguments provided herein, all bases for rejecting claims 1 and 3-11 have been rendered moot. In view of the amendments and arguments provided herein, all bases for rejecting claims 1, 3-6, 19-20, 22-23, 31 and 37 under 35 U.S.C. §102(b) over Zhang have been rendered moot and/or rebutted.

For all these reasons, claims 1, 3-23, 31 and 37 are in condition for allowance. The allowance of claims 1, 3-23, 31 and 37 is respectfully requested.

Respectfully submitted,

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